MOUTH DISSOLVING FILM: A NOVAL DISCOVERY

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Abstract: - Oral route is the best route of administration and easy route . Compared to the route of administration oral routes how best compliance Mouth dissolving film is is novel drug delivery system. It disintegrates in few minutes and reach into blood circulation. There is more patient acceptance and compliance. Recently, mouth dissolving film are gaining interest more than mouth dissolving tablets. Mouth dissolving film shows more popularity in pediatric and geriatric patients. Over the counter films are used in pain relief and motion sickness. To make mouth dissolving film mostly antiemetic, ant allergic, anti-inflammatory, etc. are used. There is fear choking in pediatric and geriatric patients. By using mouth dissolving film we can avoid first pass effect.

Keywords— Mouth, Oral, film, Tablets, dissolving, disintegration, Evaluation.

INTRODUCTION

Oral administration is a route of administration where a substance is taken through the mouth. Many medications are taken orally because they are intended to have a systemic effect, reaching different parts of the body via the blood stream, for example. Oral administration includes:

- Buccal, dissolved inside the cheek
- Sub labial, dissolved under the lip
- Sublingual administration (SL), dissolved under the tongue, but due to rapid absorption many consider as parenteral route

Enteral medications come in various forms, including oral solid dosage (OSD) forms:

Tablets to swallow, chew or dissolve in water or under the tongue

- Capsules and chew able capsules (with a coating that dissolves in the stomach or bowel to release the medication there)
- Time-release or sustained- release tablets and capsules (which release the medication gradually)
- Powders or granules

Films and oral liquid dosage forms:

- Teas
- Drops
- Liquid medications or syrups.[2]

The oral route is one of the most preferred routes of drug administration as it is moreconvenient, cost effective, and ease of administration lead to high level ofpatient compliance. The oral route is problematic because of the swallowing difficulty for pediatric and geriatric patients who have fear of choking. Patient convenience and compliance - oriented research hasresulted in bringing out safer and newer drug delivery systems. Recently, fast dissolving drug delivery system shave started gaining popularity and acceptance for the reason of rapid disintegration or dissolution, self-administration even without water or chewing. Fast dissolving drug delivery systems were first invented in the late 1970s as to overcomeswallowing difficulties associated with tablets

and capsules for pediatric and geriatric patients. Buccal drug delivery has lately become an important route of drug administration. Various bio adhesive mucosal dosage form shave been developed which includes adhesive tablets, gels, ointments, patches, and more use of polymeric films for buccal delivery, also known as mouth dissolving films. The surface of buccal cavity comprises of stratified squamous epithelium which is essentially separated from the underlying tissue of lamina propriety and submucosa by an undulating basement membrane. The permeability of buccal mucosa is approximately 4-4,000 times greater than that of the skin, but less than that of the intestine.[3]Hence, the buccal delivery serves as an excellent platform for absorption of molecules that have poor dermal penetration.[4]The primary barrier to permeability in otiral mucosa is the result of intercellular material derived from the so called,, membrane coating granules ‟present at the uppermost 200 µm layer.[5] These dosage forms have a shelf life of 2-3 years, depending on the active pharmaceutical ingredient but are extremely sensitive to environmental moisture.[6] Therefore, they are very suitable for pediatric and geriatric patients; bedridden patients; or patients suffering from dysphagia, Parkinson's disease, mucositis, or vomiting. This novel drug delivery system can also be beneficial for meeting current needs of the industry.

Compressed tablet-based systems: This system is produced using standard tablet technology by direct compression of excipients. Depending on the method of manufacture, the tablet technologies have different levels of hardness and friability. These results in varying disintegration performance and packaging needs, which can range from standard high density polyethylene (HDPE) bottles or blisters through to more specialists pack designs for product protection, for example, CIMA Labs, Pack Solv. The speed of disintegration for fast dissolving tablets compared with a standard tablet is achieved by formulating using water soluble excipients, or super disintegrate or effervescent components, to allow rapid penetration of water into the core of the tablet. The one exception to this approach for tablets is Bovril Fuisz Technology.[7] It uses the proprietary Shear form system to produce drug loaded candy floss, which is then used for tableting with other excipients. These systems can theoretically accommodate relatively high doses of drug material, including taste masked coated particles. The potential disadvantage is that they take longer to disintegrate than the thin film or lyophilized dosage forms. The loose compression tablet approach has increasingly been used by some technology houses, branded companies, and generic pharmaceutical companies, for in-house development of line extension and generic fast dissolving dosage forms.

Mouth dissolving tablet disintegrate or dissolve in saliva and are swallowed without the need for water. The offer an advantage over swallowing tablets and capsule. Difficulty to swallow is particularly experienced by pediatric and geriatric patients. Technique that are frequently employed in the preparation of mouth dissolving tablets, freeze drying, sublimations, spray drying, moulding, mass extrusion and direct compression.

History

Mouth dissolving films (MDF) were initially introduced in the market as breath fresheners and personal care products such as dental care strips and soap strips. However, these dosage forms are introduced in the United States and European pharmaceutical markets for therapeutic benefits. The first of the kind of oral strips (OS) were developed by the major pharmaceutical company Pfizer who named it as Listerine® pocket packs™ and were used for mouth freshening. Chloraseptic® relief strips were the first therapeutic oral

thin films (OTF) which contained 7 benzocaine and were used for the treatment of sore throat. Formulation of fast dissolving buccal film involves material such as strip-forming polymers, plasticizers, active pharmaceutical ingredient, sweetening agents, saliva stimulating agent, flavoring agents, coloring agents, stabilizing and thickening agents, permeation enhancers, and super disintegrates. All the excipients used in the formulation of fast dissolving film should be approved for use in oral pharmaceutical dosage forms as per regulatory perspectives.

SPECIAL FEATURES OF FAST DISSOLVING FILMS

- Film should be thin and elegant.
- Available in various size and shapes.
- Unobstructive.
- It should adhere to the oral cavity easily.
- Should processes fast disintegration without water.
- Rapid release.

ADVANTAGES OF FAST DISSOLVING FILMS

- Convenient dosing.
- No water needed.
- No risk of chocking.
- Taste masking.
- Enhanced stability.
- Improved patient compliance.
- The drug enters the systemic circulation with
- educed hepatic first pass effect.
- Site specific and local action.
- Availabilityoflargesurfaceareathatleadstorapidd isintegrationanddissolutio n within oral cavity.
- Dose accuracy
- High dose cannot be in corporated into the strip.
- he dose should be between 1- 30mg.
- Hygroscopic in nature.

The other technical challenge with these dosage forms is achieving dose uniformity.

Require special packaging for product.

IDEAL CHARACTERISTICS OF DRUG:-

The drug should have pleasant taste.

The drug to be incorporated should have low dose up to 40mg.

The drug should have smaller and moderate molecular weight.

The drug should have good stability and solubility in water as well as saliva

It should be partially unionized at the pH of oral cavity.

It should have ability to permeate the oral mucosal tissue.

CLASSIFICATION OF ORAL THIN FILM

There are three subtypes of oral fast dissolving films:

Flash release.

Mucoadhesive melt-away wafer.

Mucoadhesive sustained release wafers.

Difference between mouth dissolving film and mouth dissolving tablet

Mouth dissolving film	Mouth dissolving tablet
It is a film	It is tablet
Greater dissolution due to larger surface area	Lesser dissolution due to lesser surface area .
Better durable than tablet	Less durable as compared to film
More patient compliance	Less patient compliance than film
Only low dose can be incorporated	High dose can be incorporated

Method of preparation:

Weigh all the ingredients properly. First film forming agent solution is prepared by continuous stirring with water. Add plasticizer, surfactant, sweetening agent, saliva stimulating agent, coloring agent and flavoring agents to the above solution and stir it well. Sonicate the above solution. Add API in above solution and stir it well. Pipette out 5 ml solution in petri dish. Dry it in oven at 60°C for 5 hours and film is obtained. This method is called as kneading method.

COMPOSITION

API: a typical formulation of film contains 1 to 30 % w/w of the drug. Varieties of API can be delivered through Mouth Dissolving Film. Mostly small dose molecules are incorporated in mouth dissolving film. Many API have bitter taste. Various methods can be used to improve the edible of the formulation. Ex: Ondansetron, Aspirin, Ascorbic Acid, Diazepam, potassium iodide.

Film Forming Polymer: A variety of polymers are available for preparation of fast dissolving oral films. The use of film forming polymers in oral films has attracted considerable attention in medical and nutraceutical applications. The selection of film forming polymers, is one of the most important and critical parameter for the successful development of film formulation

The polymers can be used alone or in combination to provide desired film properties. The polymers used in oral film formulation should be :

Nontoxic and nonirritant.

Devoid of leachable impurities.

Should not retard disintegration time of film.

Tasteless

Should have good wetting and spread ability property.

Should have sufficient peel, shear, and tensile strength.

Readily available

Inexpensive.

Sufficient shelf life.

Should not aid in causing secondary infections in oral mucosa.

Plasticizers: It is the main ingredient of oral thin film. It helps to better the mechanical properties of film such as tensile strength and elongation of the film. It also minimizes the brittleness of the film and enhances the strength of polymer ex. Glycerol, propylene glycol, polyethylene glycol, castor oil.

Surfactant: They are used as wetting or solubilizing agent so that the film gets dissolved within seconds and release active agent immediately ex. SLS, tweens, benzal konium chloride, etc.

Sweeting Agent: It is mostly used as sweetener. Ex. Natural sweetener: sucrose , fructose , glucose , dextrose , etc.

2) Artificial sweetener: Saccharin , Sucralose , aspartame , etc.

Saliva stimulating Agent: They are used to increase the rate of making of saliva that would help in the faster disintegration of film ex. Citric acid, ascorbic acid, lactic acid, etc.

Flavoring Agent: Flavors used in the formulation must be non-toxic, soluble, stable and compatible with excipients. It is required in taste masking.

Coloring Agent: It is mainly incorporated for colors. It should not exceed concentration level of 1% W/W.

Packaging: Strip Packing.

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CONCLUSION

Mouth dissolving film is a novel drug delivery system. It has more patient compliance and improve efficiency. It

is preferable for pediatric and geriatric patients because there is no fear of choking. They have more advantages than other dosage form. They give rapid onset of action than mouth dissolving tablet. They can be used without any liquid. They are easy to use and dissolves rapidly. It is more durable than tablet. It has greater longevity than tablet. It is prepared by kneading method. After comparison between mouth dissolving film and mouth dissolving tablet, film has more bioavailability.

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